SUBSTITUTE FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE CITATION

ATTY. DOCKET NO.	SERIAL NO.
02-40052-US-P	10/725,064
APPLICANT: Summar	
FILING DATE December 1, 2003	GROUP TBD

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE (IF APPROPRIATE)
al	AA	4,284,647	08/18/1981	Brusilow et al.			
	AB	4,457,942	07/03/1984	Brusilow			
	AC	5,605,930	02/25/1997	Samid			
	AD	5,635,532	06/03/1997	Samid			
	AE	5,635,533	06/03/1997	Samid			
	AF	5,654,333	08/05/1997	Samid			
	AG	5,661,179	08/26/1997	Samid			
	AH	5,708,025	01/13/1998	Samid			
	AI	5,710,178	01/20/1998	Samid			
	AJ	5,712,307	01/27/1998	Samid			
	AK	5,843,994	12/01/1998	Samid			
	AL	5,852,056	12/22/1998	Samid			
	AM	5,877,213	03/02/1999	Samid			
	AN	5,883,124	03/16/1999	Samid			
	AO	5,968,979	10/19/1999	Brusilow			
	AP	6,037,376	03/14/2000	Samid			
	AQ	6,060,510	05/09/2000	Brusilow			
	AR	6,083,984	07/04/2000	Brusilow			

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OTHER DOCUMENTS *(Including Author, Title, Date, Pertinent Pages, Etc.)*

	BA	Albrecht et al., "Hepatic Encephalopathy: Molecular Mechanisms Underlying the Clinical Syndrome," J. Neurol. Sci. 1999 Nov. 30; 170(2): 138-46.

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Cey Lo	8/5/05

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	BB	Albrecht, "Roles of Neuroactive Amino Acids in Ammonia Neurotoxicity," J. Neurosci. Res. 1998 Jan. 15; 51(2): 133-8.
	BC	Applegarth et al., "Incidence of Inborn Errors of Metabolism in British Columbia," 1969-1996, Pediatrics 2000 Jan.; 105(1): e10.
	BD	Batshaw, "Inborn Errors of Urea Synthesis," Ann. Neurol. 1994 Feb.; 35(2): 133-41.
	BE	Batshaw, "Hyperammonemia," Curr. Probl. Pediatr., 1984 Nov.; 14(11): 1-69.
	BF	Becker et al., "Metabolic Disease," Textbook of Neuropathology, Baltimore: Williams & Wilkins, 1997; 487.
	BG	Breningstall, "Neurologic Syndromes in Hyperammonemic Disorders," Pediatr. Neurol. 1986 Sept.-Oct.; 2(5): 253-62.
	BH	Brusilow et al., "Urea Cycle Disorders," The Metabolic and Molecular Bases of Inherited Disease, New York: McGraw-Hill, 1995; 1: 1187-1232.
	BI	Collins et al., "Neonatal Argininosuccinic Aciduira-Survival After Early Diagnosis and Dietary Management," J. Pediatr. 1980 Mar.; 96 (3 Pt. 1): 429-31.
	BJ	Del Rosario et al., "Hyperammonemic Encephalopathy After Chemotherapy. Survival After Treatment with Sodium Benzoate and Sodium Phenylacetate," J. Clin. Gastroenterol. 1997 Dec.; 25(4): 682-4.
	BK	Feillet et al., "Alternative Pathway Therapy for Urea Cycle Disorders," J. Inherit. Metab. Dis. 1998; 21 Suppl 1: 101-111.
	BL	Felipo et al., "Molecular Mechanism of Acute Ammonia Toxicity and of its Prevention by L-Carnitine," Adv. Exp. Med. Biol. 1994; 368: 65-77.
	BM	Hauser et al., "Allopurinol-Induced Orotidinuria. A Test for Mutations at the Ornithine Carbamoyltransferase Locus in Women," N. Engl. J. Med., 1990 Jun. 7; 322(23); 1641-5.
	BN	Kuntze et al., "Hyperammonemic Coma Due to Proteus Infection," J. Urol. 1985 Nov.; 134(5): 972-3.
	BO	Logan, "Neonatal Hyperammonemic Encephalopathy. Topics in Neonatal Neurology," Orlando: Grune & Stratton 1984; 137-157.
	BP	Maestri et al., "Plasma Glutamine Concentration: A Guide in the Management of Urea Cycle Disorders," J. Pediatr. 1992 Aug.; 121(2): 259-61.

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AL	BQ	Msall et al., "Neurologic Outcome in Children with Inborn Errors of Urea Synthesis. Outcome of Urea-Cycle Enzymopathies," N. Engl. J. Med., 1984 Jun. 7; 310(23): 1500-5.
	BR	Prasad et al., "Argininemia: A Treatable Genetic Cause of Progressive Spastic Diplegia Simulating Cerebral Palsy: Case Reports and Literature Review," J. Child. Neurol. 1997 Aug.; 12(5): 301-9.
	BS	Ratnaike et al., Hyperammonaemia and Hepatoxicity During Chronic Valproate Therapy: Enhancement by Combination with Other Anticepileptic Drugs," Br. J. Clin. Parmacol. 1986 Jul.; 22(1): 100-3.
	BT	Schaefer et al., "Dialysis in Neonates with Inborn Errors of Metabolism," Nephrol. Dial. Transplant, 1999 Apr.; 14(4): 910-8.
	BU	Schutze et al., "Hyperammonemia and Neonatal Herpes Simplex Pneumonitis," Pediatr. Infect. Dis. J., 1990 Oct.; 9(10): 749-50.
	BV	Uchino et al., "Neurodevelopmental Outcome of Long-term Therapy of Urea Cycle Disorders in Japan," J. Inherit. Metab. Dis. 21 1998; 21 Suppl 1: 151-9.
	BW	Whitington et al., "Liver Transplantation for the Treatment of Urea Cycle Disorders," J. Inherit Metab. Dis., 1998; 21 Suppl 1: 112-8.
	BX	Williams et al., "Valproic Acid-Induced Hyperammonemia in Mentally Retarded Adults," Neurology 1984 Apr.; 34(4): 550-3.
	BY	Petersdorf, et al., Harrison's Principles of Internal Medicine, 10th Edition, McGraw-Hill 1983; 125, 1775, 1781, 1814-16, 2108-09.
	BZ	Beers et al., The Merck Manual of Diagnosis and Therapy, Seventeenth Edition, Merck Research Laboratories, 1999, 362-5, 372-6.
	CA	The Merck Manual, Sec. 4, Ch. 38, Clinical Features of Liver Disease, Portal-Systemic Encephalopathy, available at http://www.merck.com/pubs/mmanual/section4/chapter38/38f.htm, 6/23/2003.
	CB	What is a Urea Cycle Disorder?, available at http://www.nucdf.org/whatis.htm, 9/25/2003.
	CC	Hepatic Encephalopathy, available at http://members.tripod.com/enotes/hepatic-encephalopathy.htm, 6/24/2003.
	CD	Excerpt from Portal-Systemic Encephalopathy, available at http://www. emedicine.com/med/byname/portal-system-encephalopathy. htm, 6/24/2003.
	CE	Watanabe, Portal-Systemic Encephalopathy in Non-Cirrhotic Patients: Classification of Clinical Types, Diagnosis and Treatment Journal of Gastroenterology and Hepatology 15(9): 969-79, available at http://archive.mail-list.com/hbv_research/msg01824.html, 6/24/2003.

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OTHER DOCUMENTS ***(Including Author, Title, Date, Pertinent Pages, Etc.)***

ok	CG	Butterworth, "Effects of Hyperammonaemia on Brain Function," J. Inher. Metab. Dis. 21 (Suppl 1) 1998; 6-20.
	CH	Lee et al., "In vivo urea cycle flux distinguishes and correlates with phenotypic severity in disorders of the urea cycle," PNAS 2000 July 5; 97(14): 8021-8026.
	CI	Way, "Portal Hypertension," Current Surgical Diagnosis & Treatment, 10th edition, Appleton & Lange; 1994: 520-536.
	CJ	Ferenci et al., "Hepatic Encephalopathy-Definition, Nomeclature, Diagnosis, and Quantification: Final Report of the Working Party at the 11th World Congresses of Gastroenterology, Vienna, 1998", Hepatology 2002; 35(3): 716-721.
	CK	Sanyal et al., "Portosystemic Encephalopathy After Transjugular Intrahepatic Portosystemic Shunt: Results of a Prospective Controlled Study," Hepatology 1994; 20(1 Pt. 1): 46-45.
	CL	Riggio et al., "Hepatic Encephalopathy After Transjugular Intrahepatic Portosystemic Shunt. Incidence and Risk Factors," Digestive Diseases and Sciences, 1996 March; 41(3): 578-584.
	CM	Thuluvath et al., "TIPS for Management of Refractory Ascites. Response and Survival Are Both Unpredictable," Digestive Diseases and Science 2003 March; 48(3): 542-550.
	CN	Groeneweg et al., "Subclinical Hepatic Encephalopathy Impairs Daily Functioning," Hepatology 1998 July; 28(1): 45-49.

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